JAN 2 0 2012 K112161

RADIOMETER

510(k) Summary

AQT90 FLEX
AQT90 FLEX Myoglobin Test Kit
AQT90 FLEX Myoglobin CAL Cartridge
AQT90 FLEX LQC Multi-CHECK

Manufacturer

Radiometer Medical ApS
Aakandevej 21,
DK-2700 Bronshoj, Denmark

Contact information

Radiometer Medical ApS
Aakandevej 21
DK-2700 Bronshoj
Denmark
Att. Ms Jana S. Hellmann
Vice President Global RA/QA
Phone +45 3827 3827
Fax: +45 3827 2727
E-mail: jana.hellmann@radiometer.dk

Signature

Jana S. Hellmann

Date of preparation

January 16, 2011

Table of contents

1. Device names and classifications

- Proprietary name: AQT90 FLEX
  Class I
  Classification name: fluorometer for clinical use (21 CFR 862.2560)
  Product code: KHO

- Proprietary name: AQT90 FLEX Myo Test Kit
  Class II
  Classification name: myoglobin, antigen, antiserum, control use (21 CFR. 866.5680) Product code: DDR

- Proprietary name: AQT90 FLEX Myo CAL Cartridge
  Class II
  Classification name: calibrator, secondary (21 CFR. 862.1150)
  Product code: JIT

- Proprietary name: AQT90 LQC FLEX Multi-CHECK, Levels 1, 2 and 3
  Class I
  Classification name: quality control material (assayed and unassayed) (21 CFR 862.1660)
  Product code: JJY

2. Predicate device

- ARCHITECT STAT Myoglobin, 510(k) number K042924
- ARCHITECT STAT Myoglobin Calibrators, 510(k) number K042924
- Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537

3. Device description / test principle

The AQT90 FLEX is a cartridge-based immunoassay, based on time-resolved fluorescence using a europium (Eu) chelate as the fluorescent label. The test receptacles for the assay are 300 µL test cups, which contain the antibodies used for capture of the analyte, and the Eu chelate labeled antibodies used to trace the captured analyte. The sample is added to the test cup together with assay buffer. The cup is then incubated to allow formation of the immuno-complex, and subsequently washed to remove unbound antibodies and sample material. Finally, the cup is exposed to excitation light, and after a delay the emitted light generated by the fluorescent label

is measured by single photon counting; this measurement cycle is repeated up to 3,300 times. The total count is then compared to an assay calibration curve to obtain a quantitative measurement of the analyte's concentration in the sample.

This technology uses dried reagents deposited in the test cups and in the calibration adjustment cups – no liquids other than the sample itself together with the assay buffer are required. Total assay time is less than 20 minutes. In summary, the procedure is as follows:

1. Metering of an exact amount of sample and assay buffer and dispensing into a test cup
2. Incubating for 7-15 minutes at 37 °C
3. Washing of the test cup to remove unbound tracer antibodies and sample material
4. Drying the test cup
5. Measuring

4. Device intended use

AQT90 FLEX is for *in vitro* diagnostic use. The AQT90 FLEX analyzer is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

AQT90 FLEX Myo Test Kit includes 10 AQT90 FLEX Myo Test cartridges and one AQT90 FLEX Myo CAL cartridge. AQT90 FLEX Myo Test is an *in vitro* diagnostic assay for the quantitative determination of myoglobin in EDTA or lithium-heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is indicated for use as an aid in the rapid diagnosis of heart disease, e.g. acute myocardial infarction.

AQT90 FLEX Myo CAL cartridge is for *in vitro* diagnostic use. For calibration adjustment of the Myo Test, as indicated on the cartridge, on the AQT90 FLEX analyzer.

AQT90 FLEX LQC Multi-CHECK, Levels 1, 2 and 3, is for *in vitro* diagnostic use. For use with the AQT90 FLEX analyzer as a liquid quality control serum (LQC) to monitor the precision of laboratory testing procedures for the analytes listed on the specification insert.

5. Medical device to which substantial equivalence is claimed

The AQT90 FLEX Myo Test Kit and Myo CAL cartridges are substantially equivalent in features and characteristics to the ARCHITECT STAT Myoglobin test and ARCHITECT STAT Myoglobin Calibrators, 510(k) number K042924.

The AQT90 LQC FLEX Multi-CHECK, Levels 1, 2 and 3, is substantially equivalent in features and characteristics to the Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537.

6. Technological characteristics in comparison to predicate device

Comparison of features for AQT90 FLEX analyzer and predicate device

Item	AQT90 FLEX analyzer	ARCHITECT i System
Intended use	The AQT90 FLEX analyzer is for *in vitro* diagnostic use. It is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate concentrations of analytes in whole-blood and plasma specimens. It is intended for use in point-of-care and laboratory settings.	The ARCHITECT i System is for *in vitro* diagnostic use. It is an an immunoassay instrument based on the quantitative determination of chemiluminescense to measure and quantify analyte concentration in plasma and serum.
Test format	A completely closed, fully automated system, using cartridge-based immunoassays in disposable cups. Offers possibility of running 15 different parameters at a time and has a total capacity of 200 tests without replenishment.	The ARCHITECT i System is an open, fully-automated, immunoassay system allowing random and continuous access, and priority processing.
Specimen identification	Samples are identified from the barcode on blood collection test tube. The code is read automatically by the analyzer.	Samples are identified from the barcode on blood collection test tube. The code is read automatically by the analyzer.
Specimen sampling and handling	Blood is drawn into normal vacuum test. The blood collection tube is placed directly in the analyzer. A volume of sample is automatically drawn from the tube through its rubber seal. The still closed tube is discarded. The used immunoassay cup is discarded into a closed waste bin in the	Blood is drawn into normal vacuum test tubes, which are centrifuged to obatin plasma. The blood collection tube is placed directly in the analyzer. A volume of sample is automatically drawn from the tube through its rubber seal. The still closed tube is discarded.

Item	AQT90 FLEX analyzer	ARCHITECT i System
	analyzer.	
Calibration	The analyzer can be automatically calibrated by means of calibration cartidges at the time of test cartridge lot change.	Calibration must be carried out each time a new reagent lot number is used. Calibration is run automatically.
Quality control	AQT FLEX LQC Multi-CHECK, Levels 1, 2 and 3 is a liquid quality control. Its barcode includes upper and lower limits for the control range.	Architect STAT Controls, Levels 1, 2 and 3.

Comparison of features for AQT90 FLEX Myo Test and predicate device

Item	AQT90 FLEX Myo Test	ARCHITECT STAT Myoglobin
Intended use	The AQT90 FLEX Myo Test is an *in vitro* diagnostic assay for the quantitative determination of myoglobin in EDTA or lithium-heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is indicated for use as an aid in the rapid diagnosis of heart disease, e.g. acute myocardial infarction.	ARCHITECT STAT Myoglobin is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of myoglobin in human serum and plasma on the ARCHITECT i System with STAT protocol capability. Myoglobin values are used to assist in the diagnosis of myocardial infarction (MI).
Test format	Cartridge with 16 test cups, each coated with anti-myoglobin capture antibody and containing a separating layer as well as Eu-chelate anti-myoglobin tracer. Sample and assay buffer are added to the cup. After an incubation period the cup is washed with assay buffer and dried. When exposed to an excitation light the bound europium emits a fluorescence, which is measured in cycles of single photon counting. The total	In the 1st step, sample and anti-myoglobin coated paramagnetic microparticles are mixed and incubated. Myoglobin present in the sample binds to the anti-myoglobin coated microparticles. After washing, anti-myoglobin acridinium-labeled conjugate is added in the 2nd step. Following another incubation and wash, pre-trigger and trigger solutions are added to the reaction mixture. The resulting

Item	AQT90 FLEX Myo Test	ARCHITECT STAT Myoglobin
	count is then compared to an assay calibration curve to obtain a quantitative measurement of the analyte's concentration in the sample.	chemiluminescent reaction, which is measured as relative lights units (RLUs). A direct relationship exists between the amount of myoglobin in the sample and the RLUs detected.
Traceability	Scripps M0725	N/A
Antibodies	Mouse monoclonals for capture and tracer antibody	Mouse monoclonals for capture and tracer antibody
Sample type	Human whole blood and plasma	Human serum and plasma
Anticoagulants	EDTA, Li-heparin	Li-heparin, Na-heparin, EDTA
Controls	Recommended	Recommended
In-use stability	16 days on-board	30 days on-board
Storage temperature	2-8 °C	2-8 °C
Reportable / calibration range	Reportable range 20-900 ng/mL (µg/L)	Calibration range 0.0-1,200.0 ng/mL
Analytical sensitivity	Limit of quantitation 1 ng/mL (µg/L)	≤ 1.0 ng/mL at the 95% level of confidence
Reference range	97.5th percentile for females is 75 ng/mL (µg/L), for males 142 ng/mL (µg/L)	99th percentile for females is 106.0 ng/mL, for males 154.9 ng/mL, total 140.1 ng/mL
Imprecision	Across the reportable range, $CV(\%)_{within\text{-}run}$ is ≤ 2.5% for plasma and ≤ 3.7% for whole blood; $CV(\%)_{total}$ is ≤ 5.2% for plasma and ≤ 3.7% for whole blood	≤ 10% for myoglobin concentrations ≥ 40 ng/mL. $CV(\%)_{total}$ for controls is 3.5-4.6% at 56.7-62.3 ng/mL, 3.4-4.6% at 324.9-354.9 ng/mL, and 3.2-5.4% at 785.2-848.1 ng/mL
Interference	No significant interferences	No significant interferences
Comparison with predicate	Comparison with Abbott ARCHITECT STAT Myoglobin assay, with 157 whole blood samples in the range 24-856 µg/L (ng/mL), and 165 plasma samples in the range 22-882 µg/L (ng/mL), both with the	Comparison with Abbott AxSYM myoglobin assay, 234 samples in the range 7.6 - 1,188.7 ng/mL y = 0.99 x AxSYM + 2.88, r = 0.99

Item	AQT90 FLEX Myo Test	ARCHITECT STAT Myoglobin
	AQT90 FLEX Myo assay: $y = 1.07 \times ARCHITECT + 15$, $r^2 = 0.99$ with whole blood; $y = 1.02 \times ARCHITECT + 13$, $r^2 = 0.99$ with plasma	

Comparison of features for AQT90 FLEX Myo CAL and predicate device

Item	AQT90 FLEX Myoglobin CAL	ARCHITECT STAT Myoglobin Calibrators
Intended use	The AQT90 FLEX Myo CAL Cartridge is for *in vitro* diagnostic use. For calibration adjustment of the Myo Test, as indicated on the cartridge, on the AQT90 FLEX analyzer.	The ARCHITECT STAT Myoglobin Calibrators are for calibration of the ARCHITECT i System with STAT protocol capability when used for the quantitative determination of myoglobin in human serum or plasma.
Constituents	Each CAL Cartridge contains eight analyte-specific background cups and eight cups with added antigen	Purified cardiac myoglobin in Tris buffer with stabilizers
Calibration adjustment interval	Once per lot of AQT90 FLEX Myo Test cartridges and as often as required by relevant regulations	Upon new assay reagent lot number
In-use stability	24 hours on-board	30 days at 2-8 °C
Storage temperature	2-8 °C	-10 °C

Comparison of features for AQT90 FLEX Multi-CHECK and predicate device, the Liquicheck Cardiac Markers Plus Control LT

Item	**AQT90 LQC FLEX Multi-CHECK**	**Liquicheck Cardiac Markers Plus Control LT**
Intended use	The AQT90 FLEX LQC Multi-CHECK, Levels 1-3 is for *in vitro* diagnostic use. For use with the AQT90 FLEX analyzer as a liquid quality control serum (LQC) to monitor the precision of laboratory testing procedures for the analytes listed on the specification insert.	Liquicheck Cardiac Markers Plus Control LT is intended for use as quality control serum to monitor the precision of laboratory testing procedures listing in the package insert.
Analytes contained	Myoglobin	B-type Natriuretic Peptide (BNP), Creatine Kinase (Total), C-Reactive Protein (CRP), Homocysteine, Digitoxin, N-terminal pro-B-type Natriuretic Peptide (NT-proBNP), CKMB, Myoglobin, Troponin I, Troponin T.
Matrix	Human serum	Human serum
Storage temperature	≤ -18 °C	−20 °C to −70 °C until expiration date
In-use stability	4 days if stored unused at 2-8 °C; 2 hours if stored unused at room temperature	20 days at 2-8 °C

Summary of clinical performance data

The AQT90 FLEX Myo assay (y) was compared to the predicate device, the ARCHITECT STAT Myoglobin (x) using Li-heparin whole blood samples in the range 24-856 µg/L (ng/mL) and plasma samples in the range of 22-882 ng/mL (µg/L) with the AQT90 FLEX Myo assay. The relationship between the two methods was determined by Passing-Bablok regression. The regression lines and correlation coefficients were found to be y = 1.07 x ARCHITECT + 15, r^2 = 0.99 with whole blood, and y = 1.02 x ARCHITECT + 13, r^2 = 0.99 with plasma.

7. Conclusion

The products listed in the table are substantially equivalent based on their indications for use and performance characteristics.

New Device	Predicate Device
AQT90 FLEX Myo Test Kit. Class II. Classification name: myoglobin, antigen, antiserum, control use, (21 CFR. 866.5680), product code DDR	ARCHITECT STAT Myoglobin, 510(k) number K042924
AQT90 FLEX Myo CAL Cartridge. Class II. Classification name: calibrator, secondary, (21 CFR. 862.1150), product code JIT	ARCHITECT STAT Myoglobin Calibrators, 510(k) number K042924
AQT90 FLEX LQC Multi-CHECK, Levels 1, 2 and 3. Class I. Classification name: quality control material (assayed and unassayed) (21 CFR 862.1660), product code JJY	Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Radiometer Medical ApS
c/o Jana Hellmann
Vice President Global RA/QA
Aakandevej 21
Bronshoj, Denmark DK-2700

JAN 2 0 2012

Re: k112161
Trade Name: Radiometer Medical ApS AQT90 Flex Myo Test, AQT90 FLEX Myo CAL cartridge, AQT90 FLEX LQC Multi-CHECK, Levels 1-3 and AQT90 FLEX analyzer
Regulation Number: 21 CFR §866.5680
Regulation Name: Myoglobin immunological test system.
Regulatory Class: Class II
Product Code: DDR, JIT, JJY, KHO
Dated: January 16, 2012
Received: January 20, 2012

Dear Ms. Hellmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K112161

Device name:

AQT90 FLEX analyzer
AQT90 FLEX Myo Test Kit
AQT90 FLEX LQC Multi-CHECK, Levels 1-3
AQT90 FLEX Myo CAL Cartridge

Intended use:

AQT90 FLEX analyzer is for *in vitro* diagnostic use. The instrument is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

AQT90 FLEX Myo Test is an *in vitro* diagnostic assay for the quantitative determination of myoglobin in EDTA or lithium-heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is indicated for use as an aid in the rapid diagnosis of heart disease, e.g. acute myocardial infarction.

AQT90 FLEX Myo CAL cartridge is for *in vitro* diagnostic use. For calibration adjustment of the Myo Test, as indicated on the cartridge, on the AQT90 FLEX analyzer.

AQT90 FLEX LQC Multi-CHECK, Levels 1-3, is for *in vitro* diagnostic use. For use with the AQT90 FLEX analyzer as a liquid quality control serum (LQC) to monitor the precision of laboratory testing procedures for the analytes listed on the specification insert.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): K112161